

DATA PACKAGE BEAN SHEET

Date: 05-Aug-2019

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Decision #: 549240

DP #: (453526)

PRIA

Parent DP #:

Submission #: 1037536

E-Sub #:

*** Registration Information ***

Registration: 93167-EUP-E -

Company: 93167 - OXITEC LTD.

Risk Manager: RM 94 - Alan Reynolds - 703-605-0515 Room# PY1 S-8937

Risk Manager Reviewer: Eric Bohnenblust EBOHNEN

Sent Date: 17-Jul-2019

PRIA Due Date: 01-Nov-2019

Edited Due Date:

Type of Registration: Experimental Use Permit - Sectio

Action Desc: (B620) New Active Ingredient, Experimental Use Permit application; NON-FOOD USE INCLUDIT

Ingredients: 006002, Tetracycline-repressible Transactivator Protein Variant (tTAV) protein and the genetic n

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 05-Aug-2019

Due Back:

DP Ingredient: 006002, Tetracycline-repressible Transactivator Protein Variant (tTAV) protein and the genetic n

DP Title: Human Health - 10 day letter response

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: BPPD / ETB

Last Possible Science Due Date: 02-Oct-2019

Team Name: Biotech Science Team

Science Due Date:

Reviewer Name: Striegel, Wiebke

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

Wiebke,

Please review and determine the acceptability of the following MRIDs to support the human health risk assessment. 50889401, 50889402,, 50889403, 50889404, 50889405, 50889406, 50889417, 50889418, 50889419, 50889420, 50889421, 50889422, 50889424, 50889425, 50889426, 50889427.

All MRIDS (they are not linked in OPPIN), application, CSF's, label, cover letter and any other supporting documents can be found in documentum. Let me know if you can't find anything.

Thanks.

Eric

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